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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,977	12/15/2004	Martin Eberle	70070	1939

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EXAMINER	
SHIAO, REI TSANG	

ART UNIT	PAPER NUMBER
1626	

MAIL DATE	DELIVERY MODE
06/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/517,977	EBERLE ET AL.	
	Examiner	Art Unit	
	Rei-tsang Shiao, Ph.D.	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,12 and 13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10,12 and 13* is/are rejected.

7)☒ Claim(s) *1-9* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/15/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This application claims benefit of the foreign application:

UNITED KINGDOM 0214116.6 with a filing date 06/19/2002.

2. Claims 1-10 and 12-13 are pending in the application.

Information Disclosure Statement

3. Applicant's Information Disclosure Statement, filed on December 15, 2004, has been considered. Please refer to Applicant's copy of the 1449 submitted herein.

Responses to Election/Restriction

4. Applicant's election with traverse of election of Group III claims 1-10 and 12-13, in part, in the reply filed on May 15, 2007 is acknowledged. As a single disclosed species of Example 1, i.e., 2-(4-chlorophenoxy-methyl)-2-benzylsulfonylamino-propionitrile, is also acknowledged. The traversal is on the grounds that Jones US 5,317,005 fails to teach this common moiety shared by all compounds of the present invention.

This is found not persuasive, and the reasons are given *infra*.

Claims 1-10 and 12-13 are pending in the application. The scope of the invention of the elected subject matter is as follows.

Claims 1-10 and 12-13, in part, drawn to compounds of formula (I), wherein the variable Ar_1 represent an optionally substituted aryl thereof, **when** the variable Ar_2 represents a heteroaryl group, the heteroaryl is selecetd from pyridyloxy, pyridyl,

pyrimidinyloxy, pyrimidinyl, pyrazolyl, thiazole, thiazolyloxy, triazole, triazolyloxy, oxadiazole, or imidazole thereof, the variables Ar_1, X, W, R_1-R_8 independently do not represent heteroaryl or heterocycle thereof, and the variables Ar_1, X, W, R_1-R_8 independently are not substituted with heteroaryl or heterocycle thereof, and their processes of making and methods of use.

The claims 1-10 and 12-13 herein lack unity of invention under PCT rule 13.1 and 13.2 since the compounds defined in the claims lack a significant structural element qualifying as the special technical feature that defines a contribution over the prior art, see Alberte et al. US 7,132,567. Alberte et al. disclose similar aryl/sulfonyl compounds for combating fungus, see columns 7 and 17-18. Accordingly, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper. Furthermore, even if unity of invention under 37 CFR 1.475(a) is not lacking, which it is lacking, under 37 CFR 1.475(b) a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations:

(1) A product and a process specially adapted for the manufacture of said product', or

(2) A product and a process of use of said product; or

(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

And, according to 37 CFR 1.475(c)

> if an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b), unity of invention might not be present.

However, it is noted that unity of invention is considered lacking under 37 CFR 1.475(a) and (b). Therefore, since the claims are drawn to more than a product, and according to 37 CFR 1.475 (e)

> the determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

The claims lack unity of invention and should be limited to only a product, or a process for the preparation, or a use of the said product. In the instant case, Groups I-III are drawn to various products, processes of making, methods of use, and the final products do not contain a common technical feature or structure, and do not define a contribution over the prior art, i.e., similar aryl/sulfonyl compounds of Alberte et al. '567. Moreover, the examiner must perform a commercial database search on the subject matter of each group in addition to a paper search, which is quite burdensome to the examiner.

Claims 1-10 and 12-13, in part, embraced in above elected subject matter, are prosecuted in the case. Claims 1-10 and 12-13, in part, not embraced in above elected subject matter, are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

The requirement is still deemed proper.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10 and 12-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for using compounds/compositions of formula (I) for controlling fungus, it does not reasonably provide enablement for using compounds of formula (I) for controlling microorganisms without limitation. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

In the instant case:

The nature of the invention

The nature of the invention of claims 10 and 12-13 is drawn to intent methods of use using compounds of formula (I) controlling microorganisms without limitation, see claims 10 and 12.

The state of the prior art and the predictability or lack thereof in the art

The state of the prior art is that the pharmacological art involves screening *in vitro* and *in vivo* (i.e., applied on plant per se) to determine which compounds exhibit the desired pharmacological activities (i.e. what compounds can treat which specific diseases by what mechanism). There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic or preventive regimen on its face.

The instant claimed invention is highly unpredictable as discussed below:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F.2d 833,166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. Alberte et al. US 7,132,567. Alberte et al. disclose similar aryl/sulfonyl compounds for combating fungus, see columns 7 and 17-18. Applicants are claiming intent methods of use using compounds of formula (I) effective to "controlling microorganisms" without limitation. As

such, the specification fails to enable the skilled artisan to use the compounds of claims 10 and 12-13 effective to "controlling microorganisms" without limitation.

In addition, there is no established correlation between *in vitro* activity and accomplishing treatment of "controlling microorganisms" without limitation, *in vivo*, and those skilled in the art would not accept allegations in the instant specification to be reliable predictors of success, and those skilled in the ad would not be able to use the compounds of formula (I) since there is no description of an actual method wherein "controlling microorganisms" without limitation in a host is treated.

Hence, one of skill in the art is unable to fully predict possible results from the administration of the compounds of claims 10 and 12-13 due to the unpredictability of the "controlling microorganisms" without limitation. The "controlling microorganisms" without limitation is known to have many obstacles that would prevent one of ordinary skill in the art from accepting treating regimen on its face.

The amount of direction or guidance present and the presence or absence of working examples

The only direction or guidance present in the instant specification is the listing of exemplary assays, i.e., see page 74 of the specification. There are no *in vitro* or *in vivo* working examples present for the controlling microorganisms other than fungus of by the administration of compounds of the instant invention.

The breadth of the claims

The breadth of the claims is a methods of use of the instant compounds effective to "controlling microorganisms" without limitation.

The quantity of experimentation needed

The quantity of experimentation needed is undue experimentation. One of skill in the art would need to determine what "controlling microorganisms" would be benefited by the administration of the instant compounds of formula (I) of the instant invention and would furthermore then have to determine which of the claimed methods of use would provide controlling microorganisms other than controlling fungus, if any.

The level of the skill in the art

The level of skill in the art is high. However, due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by *in vitro* and *in vivo* screening to determine which methods of use exhibit the desired pharmacological activity and which diseases would benefit from this activity. Thus, the specification fails to provide sufficient support of the broad use of the pharmaceutical compounds of the instant claims 10 and 12-13 for the "controlling microorganisms" without limitation. As a result necessitating one of skill to perform an exhaustive search for which "controlling microorganisms" without limitation, can be treated by what pharmaceutical compounds of the instant claims in order to practice the claimed invention.

Genentech Inc. v. Novo Nordisk A/S (CA FC) 42 USPQ2d 1001, states that " a

patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the Wands factors and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation, with no assurance of success. This rejection can be overcome by deletion of the preamble " for controlling and protecting against phytopathogenic microorganisms" of claim 10, and incorporation of the limitation "microorganisms" (i.e., fungus) into claim 12, would obviate the rejection.

Claim Objections

6. Claim 1-10 and 12-13 are objected to as containing non-elected subject matter, i.e., heteroaryl or heterocyclic ring. It is suggested that applicants amend the claims to the scope of the elected subject matter as defined on pages 2-3 *supra*.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rei-tsang Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rei-tsang Shiao, Ph.D.
Patent Examiner
Art Unit 1626

June 18, 2007